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DEPARTMENT OF COMMERCE

International Trade Administration

Healthcare Trade Mission to Russia, June 3-7, 2013

AGENCY: International Trade Administration, Department of Commerce

ACTION: Notice

Mission Description

The U.S. Department of Commerce, International Trade Administration, U.S. and Foreign Commercial Service (CS), is organizing a Healthcare Trade Mission to Moscow and St. Petersburg, Russia from June 3-7, 2013 which will be led by a senior Commerce official.

Russia, with 140 million consumers and rapidly growing demand for healthcare products and services, presents lucrative opportunities for U.S. companies. Equipment, technologies, and investments are needed in the healthcare sector, specifically in the medical equipment, dental equipment and biotechnology sub-sectors. This healthcare mission will directly contribute to the National Export Initiative (NEI) by assisting U.S. businesses in entering the Russian healthcare market and increasing U.S. exports. It will also be a deliverable for the U.S.-Russia Bilateral Presidential Commission Business Development and Economic Relations Working Group.

The mission will help participants gain market insights, make industry contacts, solidify business strategies, and advance specific projects with the goal of increasing U.S. exports to Russia. The mission will include one-on-one business appointments with pre-screened potential partners, market briefings, and networking events. Joining this official U.S. delegation will provide participating companies an opportunity to assess the Russian healthcare market.

Commercial Setting

Russia is one of the world's fastest growing economies and its healthcare system is evolving rapidly with a promising outlook for U.S. healthcare exports, particularly in the medical equipment, dental equipment and biotechnology subsectors. Russia's National Health Project aims at improving access and funding for healthcare and improving Russia's healthcare sector, and has created opportunities for increased U.S. exports in the healthcare sector.

Approximately 20% of overall health care spending is covered out-of-pocket by patients.

Voluntary healthcare insurance programs currently account for approximately one-third of total private healthcare expenditures. According to future reform plans, mandatory insurance funds will serve as the main source of healthcare funding and will provide transparency and monetary control within the system.

The National Health Project was signed by President Putin in 2005 and was designed to significantly improve Russian healthcare. From 2011-2013, \$15.4 billion was allocated from both the federal budget and the Mandatory Healthcare Insurance Fund [to the National Health Project?]. The Program of Modernization in Healthcare 2011-2012, aimed at renovating and

upgrading healthcare facilities, was financed at \$11 billion. The significant funding reflects the current need for new modern technologies for diagnostics and treatment. Russian patients are becoming more aware of modern medical technologies around the world and expect the same types of treatment in Russia.

In addition to these programs that are currently being implemented, the Ministry of Health has recently developed a draft government program called “Development of Healthcare in the Russian Federation.” This document is currently under review for approval. It contains the principles of preventive medicine, quality of provided healthcare services, education of medical personnel, and overall changes in the healthcare infrastructure.

The Ministry of Industry and Trade is also currently developing a strategy for the development of the medical industry through 2020. With continued growth in this sector, World Trade Organization (WTO) accession, and government plans to modernize and invest in Russian healthcare through 2020, American companies should be poised to make significant contributions to the Russian healthcare market.

Medical Equipment

The medical equipment sector is one of the fastest-growing sectors of the economy. There is a relatively stable macroeconomic situation in Russia with much unsatisfied deferred demand for medical equipment across the country. In addition, the Russian government is focused on this

sector and has increased government financing for the purchase of medical equipment. For example, the Program of High-Tech Medical Assistance 2011-2013 was financed at \$4 billion.

In 2011, the market for medical equipment was estimated at \$4.9 billion. During the next nine years, experts expect yearly market growth to be 13.5%. The most promising market segments include diagnostics and visualization, cardiovascular, ophthalmology, orthopedics, laboratory diagnostics and urology equipment and technology. For example, the average annual increase from 2006-2011 in market share for diagnostics and visualization equipment was 18% and in medical IT 10%.

Since commercialization of medical equipment manufactured in Russia remains low, the market for medical equipment is heavily dependent on imports. The average annual increase in the import market for medical equipment from 2006 to 2011 was approximately 23%. Medical equipment imports in 2006 were \$14.2 billion, with steady growth to \$41 billion in 2011.

Membership in the WTO will also benefit foreign exports to Russia. After full implementation of the WTO accession and Permanent Normal Trade Relations, tariffs for medical equipment are estimated to range from 0% to 7%. Currently, tariffs range as high as 15% to 20%.

Dental Equipment

The Russian dental market is also a sector that is expanding and showing good growth potential. In 2011, total world imports into Russia for dental equipment were approximately \$500 million,

reflecting the need for dental equipment for use in the large market for dental services in Russia, which was approximately \$6 billion in 2011.

The number of clinics, practicing dentists, technicians and patient visits are all on the rise. There are over 9,500 dental units operating in Moscow, with 3,000 state clinics and over 6,500 private clinics. There are 670 municipal dental clinics and 2900 dental departments within those clinics. The highest level of dental industry privatization is in the Moscow region.

The number of practicing dentists in Russia is 68,000, of which 35,000 are members of the Russian Dental Association. The number of patient visits is approximately 150 million a year. However, the ratio of dentists to patients in Russia is still only 45/100,000 people, which is below levels in the United States and most European countries. In the United States, the ratio of patients to dentists is 60/100,000.

The dental market is one of the most organized markets in Russia. The largest associations are the Russian Dental Association, which has 69 regional divisions and the Dental Industry (DI ROSI) which has 45 member companies. These associations play an important role in the introduction of new technologies and practices, actively participate in trade events, and regularly publish in professional journals. As a result, they have a large impact on the industry. The two major dental universities are Moscow State Medical and Dental University and the Sechenov Medical Academy in Moscow.

Domestic production of dental equipment is insufficient for the Russian market and very few

new products are produced domestically. Local manufacturers such as Avera, VladMiVa, Raduga Rossii, Geosoft, Stomadent Omega, and Tselit produce a wide range of dental equipment. Since Russia's domestic dental production level meets only 20% of total demand, imports play a significant role in the market. The majority of dental equipment is supplied from the United States, Germany, France, Switzerland, Japan, and other countries.

Many large U.S. and international companies have offices in Russia, including Dentsply, 3M, Nobel Biocare, Mileston, Midmark, 3i, Sirona, Kavo, Colgate, Kodak-Eastman, Philips-Sonicare, Dentsply Dental (now owned by Philips), Oral B, and Wm. W. Wrigley Jr. Co.

There are about 500 distributors of dental equipment in Russia. The major distributors are located in Moscow and work in other regions through smaller local distributors or through regional representatives. Import customs clearances are executed more easily in larger cities like Moscow and St. Petersburg. There are strict product registration and certification procedures necessary for the release of dental equipment into the market. The registration and certification process can be complicated, time-consuming, and expensive. It may require a regular market presence by the manufacturer or an authorized representative with competent Russian language skills and knowledge of the local market to be able to complete the process.

Biotechnology

In the last several years, Russia has been developing an innovative modern economy by focusing on information technologies and nanotechnologies. The biotechnologies area has large potential

and is underdeveloped, but is evolving because of the need to extend life expectancies within the country. Large U.S. multinational companies like Celgene, Amgen, and Genzyme are established in the market and are already working in the biotechnology field. Despite the fact that major companies from Europe and the U.S. have already entered the market, there is still room for small innovative companies in the biotechnology area. Good examples include two small U.S. biotechnology companies, Bind and Selecta, which have recently opened offices in Russia to start research and development, which is a priority of the Russian government.

The Government Commission on High Technologies and Innovations signed a decision in April, 2011 to create a State Coordination Program for the Development of Biotechnology in the Russian Federation through 2020. The Ministry of Economic Development is responsible for this State Coordination Program, which focuses on several areas including biopharmaceuticals and biomedicine.

1. Biopharmaceuticals (essential medicines, including biogenerics, hormones, cytokines, therapeutic monoclonal antibodies, peptides, phytomedicines, new generation vaccines, antibiotics and bacteriophages)

2. Biomedicine (molecular diagnostics, personalized medicine, engineered cell and tissue for therapeutic purposes, biocompatible materials)

The Russian market for biopharmaceuticals in 2010 was estimated at \$2.2 billion, of which \$1.3 billion was dedicated to cytokines, genetically engineered hormones (including insulin),

coagulants and therapeutic enzymes, monoclonal antibodies (\$350 million), and vaccines (\$350 million). For example, the sales of antibodies and vaccines are expected to rise to \$480 million and \$370 million respectively by the year 2015.

The Russian biotechnology market is focused on the development and manufacturing of products for the diagnosis and treatment of human diseases and for the prevention of harmful effects of the environment on humans. The world market for biotechnology (used for molecular genetics diagnostic technologies) was \$13.5 billion in 2010, and is expected to be \$33.3 billion by 2015. The access to credible data for the Russian market is low because the segment has not been fully developed, but it is expected to mature in the near future.

Biotechnology is a large part of the overall pharmaceutical sector. According to industry experts, Russia is currently one of the ten largest pharmaceutical markets in the world. In 2011, the pharmaceutical market volume amounted to \$26 billion in end user prices, which is 12% higher than in 2010.

An important recent trend was the planning and formation of “pharmaceutical clusters”. This was due in part to the completion of the “Strategy of Development of the Pharmaceutical Industry-2020”, developed by the Ministry of Industry and Trade which outlines some government priorities.

The Russian pharmaceutical market is import driven with 76% of drugs taken in Russia produced abroad. The only domestic manufacturer in the top 20 leading players in the Russian pharmaceutical market is Pharmstandart.

MISSION GOALS

The goal of the Healthcare Trade Mission to Russia is to promote the export of U.S. goods and services by: 1) introducing U.S. companies to industry representatives and potential clients and partners; and 2) introducing U.S. companies to industry experts to learn about policy initiatives that will impact the Russian healthcare industry in general as well as the medical equipment, dental equipment and biotechnology sectors.

MISSION SCENARIO

In Moscow, trade mission members will participate in an Embassy briefing from industry experts and take part in one-on-one business appointments with private-sector organizations. In addition, they will enjoy a networking event with industry leaders and potential partners. In St. Petersburg, all of the delegates will have customized one-on-one business appointments and attend another networking reception.

Matchmaking efforts will involve partners such as the Association of International Pharmaceutical Manufacturers (AIPM), Innovative Pharma, Association of International Manufacturers of Medical Devices (IMEDA), the American Chamber of Commerce in Russia, and the Russian Dental Association. U.S. participants will be counseled before, during, and after the mission by CS Russia staff actively involved in the healthcare trade mission.

Proposed Time Table

Monday June 3 <u>Day 1</u>	Moscow Briefing by the U.S. Embassy and industry experts Site Visits in afternoon
Tuesday June 4 <u>Day 2</u>	Moscow One-on-one business appointments Networking reception
Wednesday June 5 <u>Day 3</u>	Depart for St. Petersburg Travel day and free evening in St. Petersburg
Thursday June 6 <u>Day 4</u>	St. Petersburg One-on-one business appointments Networking reception

Friday	St. Petersburg
June 7	Additional meetings and follow-up appointments
<u>Day 5</u>	Departure for the United States (Friday evening or Saturday, June 8)

Participation Requirements

All parties interested in participating in the trade mission must be active in the healthcare sector and complete and submit an application package for consideration by the Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as outlined below. A minimum of 10 and maximum of 13 companies will be selected to participate in the mission from the applicant pool. Applicants that are U.S. companies already doing business in Russia as well as those seeking to enter the Russian market for the first time may apply.

Fees and Expenses

After a company has been selected to participate in the mission, a payment to the Department of Commerce in the form of a participation fee is required. The participation fee will be \$5950 for large firms and \$5350 for a small or medium-sized enterprise (SME) trade association, which

will cover one representative.*¹ The fee for an additional representative (SME/trade association or large company) is \$750, which will cover one representative. The fee for an additional representative (SME or large company) is \$750.

Expenses for travel, lodging, meals, and incidentals will be the responsibility of each mission participant. Delegation members will be able to take advantage of U.S. Embassy rates for hotel rooms beginning Sunday, June 2 in Moscow and through Saturday, June 8 in St. Petersburg. Please note that the trade mission begins in Moscow and ends in St. Petersburg. Early arrival nights in Moscow, return transportation to Moscow from St. Petersburg, or the extension of stay in St. Petersburg will be the responsibility of the participants.

Conditions for Participation

An applicant must submit a completed and signed mission application and supplemental application materials, including adequate information on the company's products and/or services, primary market objectives, and goals for participation. If the Department of Commerce receives an incomplete application, the Department may reject the application, request additional information, or take the lack of information into account when evaluating the applications.

¹ An SME is defined as a firm with 500 or fewer employees or that otherwise qualifies as a small business under SBA regulations (see <http://www.sba.gov/services/contractingopportunities/sizestandardtopics/index.html>). Parent companies, affiliates, and subsidiaries will be considered when determining business size. The dual pricing reflects the Commercial Service's user fee schedule that became effective May 1, 2008 (see <http://www.export.gov/newsletter/march2008/initiatives.html> for additional information).

Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have at least 51 percent U.S. content of the value of the finished product or service. In the case of a trade association, the applicant must certify that for each company to be represented by the association, the products and/or services the represented company seeks to export are either produced in the United States or, if not, marketed under the name of a U.S. firm and have at least fifty-one percent U.S. content.

Criteria for Participation

Selection will be based on the following criteria:

- Suitability of the company's (or in the case of a trade association, member companies') products or services to the market.
- Applicant's (or in the case of a trade association, member companies') potential for business in Russia and in the region, including likelihood of exports resulting from the mission.
- Consistency of the applicant's (or in the case of a trade association, member companies') goals and objectives with the stated scope of the mission.

Diversity of company size, sector or subsector, and location may also be considered during the review process.

Referrals from political organizations and any documents containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and not considered during the selection process.

Timeframe for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the Federal Register, posting on the Commerce Department trade mission calendar (<http://www.ita.doc.gov/doctm/tmcal.html>) and other Internet web sites, press releases to general and trade media, direct mail, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows. The U.S. Department of Commerce will begin reviewing applications and making selection decisions on a rolling basis beginning on December 28, 2012 until the maximum of 20 participants is selected. Applications received after March 15, 2013 will be considered only if space and scheduling constraints permit.

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